Title page

Category of paper: Original Article

Title: Comparative study on the mechanical behaviour of polyurethane PICCs

Short Title: PICCs material comparative Study

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Funding resources: SIGIAV (Scientific Italian Society of Implant and management of vascular access)

Abstract

Purpose: This study describes a comparative analysis of eight commercial polyurethane, single-lumen peripherally inserted central venous catheters (PICCs) from different vendors. The aim was to investigate the mechanical response of the catheters providing objective and quantitative data to support a comparison among them. Such data could help nurses and physicians to select a central venous catheter (CVC) based not only on the expected duration of dwell or an assessment of the vessels at the desired insertion site, but also on the chemical and mechanical properties of the CVC and the projected response of the body to these properties.

Methods: An experimental procedure was defined and tests performed to assess some main characteristics of the PICC lines including: macro and micro geometric features, chemical and physical properties, and mechanical response. Preliminary measurements were performed to accurately define all geometric characteristics including length, inner and outer diameters, and any inherent initial curvature of the catheter. Micro-geometric features were investigated using surface roughness analysis, optical microscopy, Scanning Electron Microscopy. Mechanical properties were studied by means of both Dynamical-Mechanical Thermal Analysis, simple uniaxial tensile tests, relaxation time characteristics and kinking tests.

Results: Results are discussed in order to compare the different PICC lines. In particular, they show that polyurethane catheters can have different mechanical behavior, which might play a role in the onset of pathologic processes and result in increased risk and incidence of catheter related complications.

Conclusions: This study provides useful information which can help identifying and facilitate the choice of a PICC.

Key words: Comparative study, Mechanical properties, PICCs

Introduction

Since their introduction in the 1970s, clinical use of peripherally inserted central venous catheters (PICCs) has continuously increased, becoming a widespread solution for long-term treatments with over 3 million placements each year in the U.S. alone (1). It has been estimated that the U.S. PICC market was worth nearly $ 413 million in 2011, and it is expected to reach over $ 583 million by 2017 (2). Because of both medical requirements and availability of new technologies and materials, many new PICC products have been launched on the market in recent years, characterized by both design improvements and the use of new materials. Often, these devices are developed in order to either possess particular features or to meet a specific purpose in clinical practice. Typical examples include valved PICCs and power-injectable PICCs. The market spread of power-injectable PICCs, in particular, has progressively risen and now constitutes a majority of the PICC market since they are generally preferred by physicians and hospitals for their great versatility, despite their higher cost. Undoubtedly, most of the success of power-injectable PICCs can be attributed to the fact that they are typically made of polyurethane rather than silicone, the most common material of conventional, non-power-injectable PICCs. However, beyond the well appreciated technical improvements of these new devices, the use of polyurethane for manufacturing PICCs raises some concerns regarding the intrinsic variability of chemical and mechanical properties of materials belonging to this class. It is a fact that, depending on how they are synthesized and processed, polyurethanes can exhibit very different levels of properties such as: mechanical stiffness, pressure strength, chemical stability and biocompatibility. In this context, the fact that neither widely recognized testing procedures nor well defined target properties are available, together with the lack of information regarding the material properties of commercial polyurethane

PICCs, raises important questions about how a trustworthy “quality” level of product can be defined and assessed. Thus, independent studies that define and assess the relevant properties of commercial PICC materials have become a necessity in order to improve customer awareness and allow clinicians to make correct product choices based on patient needs and requirements. In this direction, recently, the effectiveness of valved versus non-valved PICCs has been discussed in (2) on the basis of a clinical trial.

From a mechanical point of view, there are two main requirements for a PICC: 1) suitable flexibility for reducing procedure risks and patient discomfort during insertion and removal of the catheter, and 2) a structural strength capable of withstanding pressure during injection of fluids (3). The catheter flexibility, and particularly its bending stiffness, is most important at the tip, while the pressure strength is often improved by increasing the wall thickness at the PICC connection. Thus, the proximal and distal parts of a PICC may have different mechanical and chemical characteristics. While there is no data in the literature regarding the mechanical properties of commercial PICCs, nor indications or comparisons of their behavior, many studies can be found on the polyurethane material itself, e.g. (4,5), which changes from manufacturer to manufacturer. The aim of this investigation is to compare 5 Fr PICCs for long-term infusion from eight major manufacturers based on the mechanical and chemical properties of the polyurethane catheter. Preliminary evaluation included some geometrical features such as length, inner and outer diameters and the initial curvature of the catheter. A final goal of this complex study is to provide helpful information to nurses and physicians for selecting a central venous catheter (CVC) based not only on duration of dwell or insertion site, but also on the chemical and mechanical properties of the central venous catheter and the body’s projected response to these properties.

Materials and Methods

Samples

In this study, samples of 5 Fr, single lumen polyurethane catheters were analyzed, selecting eight products from eight different manufactures: Alphamed (Italy), BARD (USA), Cook (USA), Vygon (France), BBraun (Germany), AngyioDynamics (UK), Healthline (USA), Argon (USA). In Table 1 manufacturer, model, and type (PI=power injectable, NPI=non-Power-Injectable) of the samples are detailed.

As an Appendix to this paper, a background with an introduction of the main concepts of polyurethane material and mechanical tests can be found online.

Table 1: PICC samples data.

ID	Manufacturer	Country	Model	Type
A	Alfamed	Italy	MD 01 02282	NPI
B	Bard	USA	6175118 Power picc	PI
C	Cook	USA	G12987 TurboFlo	NPI
E	Argon	USA	384465 L-Cath	NPI
F	Vygon	Francia	1294.115 Lifecath PICC	NPI
G	BBraun	Germany	044 39002 Celsite PICC-Cel	PI
H	AngioDynamics	UK	12102603	PI
I	HealthLine	USA	A14H-05160	NPI

The ID is used is used for labelling results. Type distinguishes between power-injectable (PI) and non-power-injectable (NPI) catheters.

Test procedure

The following procedure was defined for the analysis of each sample:

a) The composition, weight and volume of the kit containing the PICC were recorded before extracting and labeling the catheter. Packaging influences the direct cost of the product including logistics, transportation and stocking.

b) Particular attention was paid to the method in which the PICC was conserved within the package: free or inside a rigid cover, with stylet inserted or not. In order to evaluate the effect of conservation method, the initial shape of the catheter was reconstructed by image processing. The PICC was suspended under self-weight and pictures were taken with and without the stylet inserted. As an indicator of the initial shape, the distance (d_e) between the endpoints H and F was calculated by means of a specific Matlab code and normalized with respect to the catheter nominal length l_n (Figure 1). For an ideal straight PICC, the ratio d_e/l_n would be equal to one; thus, for each sample, results will report the percentage values of the ratio d_e/l_n as a measure of its straightness.

It is important to note that the initial shape of the PICC was investigated because this may condition the ease of insertion in patients. Additionally, the comparison of the initial shape of the catheter with and without a stylet provides information about the relative stiffness of the catheter, which is pertinent when considering insertion procedures.

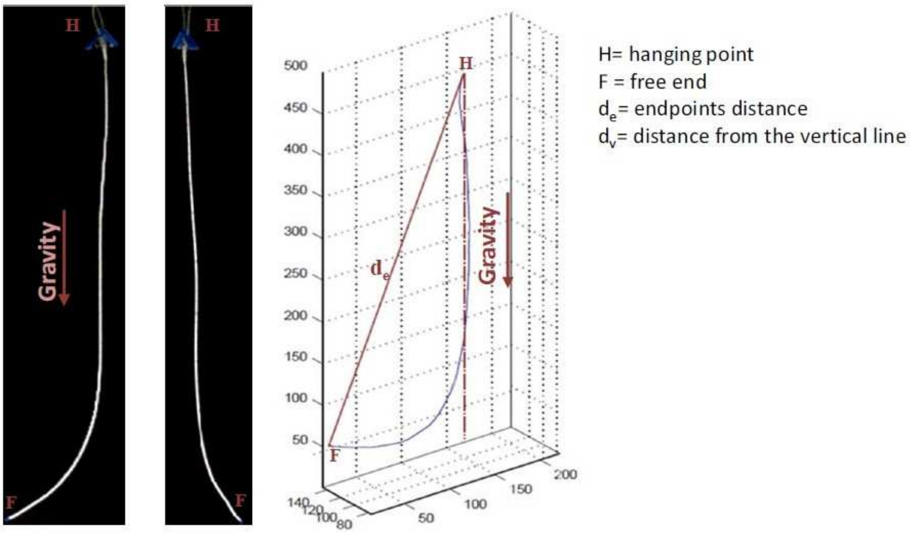


Figure 1: Geometrical features to assess the initial shape of the PICC

c) A microscope was used to measure **internal diameter** and **wall thickness** of the PICCs at the distal end, while the **external diameter** was assessed along the whole catheter length by means of macro pictures. These values were then compared with the corresponding nominal ones provided by each vendor.

d) In addition to the *macroscopic* geometrical features, the outer and inner surfaces of PICCs were analyzed at micro-scale using scanning electron microscope (**SEM**) images with a magnification of 90x for the external surface and 4000x for the internal surface. Two **surface roughness** parameters, the arithmetic average surface roughness R_a and the maximum height of the peaks R_t , were measured on samples 30mm long and cut from the distal end (6).

e) As a first analysis on the mechanical behavior of PICCs, **kinking tests** were performed in which a sample is shaped in a loop, then pulled at constant speed until kinking occurs. As a measure of the kinking strength, the length l_k in the critical configuration was determined (Figure 2). This test is useful to understand when PICC operational conditions may become dangerous resulting is a collapse of the catheter lumen.

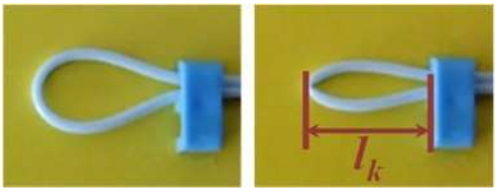


Figure 2: Kinking test: initial loop (left) and kinking cross section (right).

f) In order to investigate the mechanical properties of the PICCs, **tensile tests** were performed on some small samples, with lengths varying from 40-50 mm. A strain rate of 0.1 min^{-1} was applied until a 30% elongation was reached. Tests were performed at room temperature (24-27°C).

g) Finally, the visco-elastic response of PICCs was investigated by means of Dynamical Mechanical Thermal Analysis (**DMTA**). In these tests, a 1 Hz sinusoidal strain of 0.1%

amplitude with a 0.3% bias was applied to small samples and the corresponding reaction force at any total strain level was measured while simultaneously increasing the temperature from -100°C to 100°C at 2°C/min.

Results

Packaging

PICC packaging varies significantly from vendor to vendor; the kit weight ranges from 0.14 kg to 1 kg. Additionally, individual boxes contained from 9 to 57 items, although less than 10 of them are typically used.

Initial shape

As described in the test procedure section, the initial shape of the PICC under self-weight was analyzed by image processing Figure 3 shows synthetic results of the distance between the endpoints normalized to the length of each catheter with or without stylet.

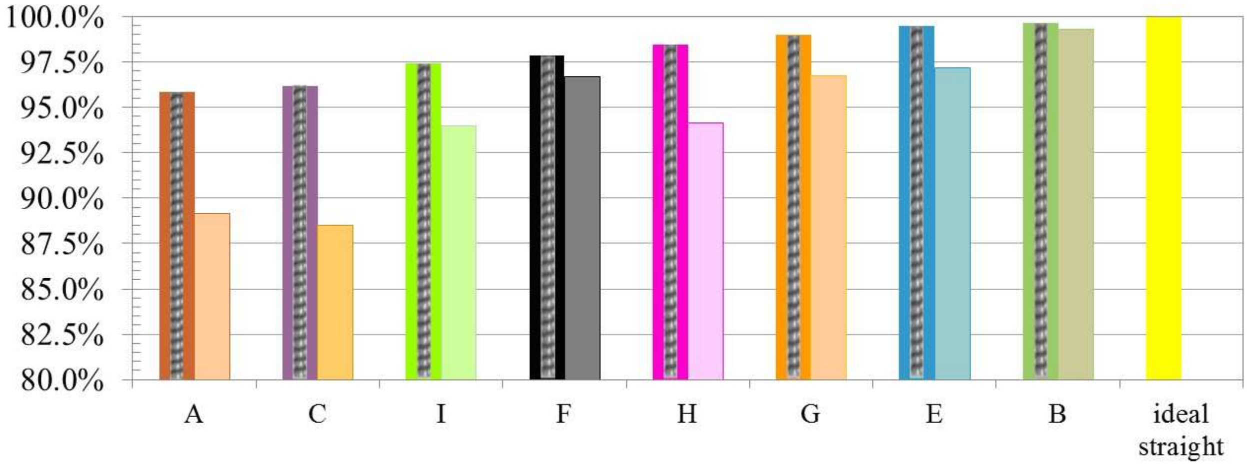


Figure 3: Catheter endpoints distance under self-weight (Figure 1) scaled by its effective length, in percentage values. For each sample the left bar represents the ratio for the PICC with guidewire while the right without it. The yellow bar (on the right) represents the ideal straight PICC

It can be observed that all the samples with stylet inside are almost straight (straightness>95%); there are cases in which the presence of the stylet straightened the catheter, as observed in the first two samples in Figure 3, and other cases in which the endpoint distance remains almost unchanged with and without the stylet. This different behavior can be attributed to both the relative stiffness of the polyurethane PICC, the stylet and the way the catheter was packaged.

The initial shape of the PICC with the stylet can have an impact on the insertion procedure. However, in the absence of the stylet, we gain information about the position that the PICC will tend to maintain after it is in place for operation.

Geometrical features

Results of the geometrical features of catheters are reported in Table 2, including outer/inner diameters, thickness, and actual and declared lengths. Although all selected samples are marked as 5 Fr (1.65mm), the outer diameters were found to vary from 1.64 mm to 1.76 mm in six samples. Two samples presented a peculiar tapered geometry, larger at the proximal end followed by a constant diameter towards the distal end. In particular, in sample B, the external diameter varied from 2.08 mm to 1.63 mm in the initial 80 mm length while in sample C, the diameter varied from 2.3 mm to 1.7 mm in the first 92 mm length. The reason for such a design may be to increase stiffness closer to the end so as to withstand injection pressure.

Table 2: PICC geometrical features. In the last column the measured and the declared length of the PICC are reported. Diameters and thickness refer to the uniform (not tapered) segment.

Sample	*Outer diameter* $2\, r_o$ (mm)	*Inner diameter* $2\, r_i$ (mm)	*Thickness* (mm)	*Length (nominal)* (cm)
A	1.66	0.98	0.34	55.3 (55)
B	2.08-1.63	0.87	0.38	56.7 (55)
C	2.3-1.7	1.25	0.22	60.0 (60)
E	1.73	1.28	0.22	60 (60)
F	1.74	1.18	0.28	60.2 (60)
G	1.64	0.89	0.37	61 (60)
H	1.74	1.22	0.26	65.1 (65)
I	1.76	1.03	0.36	61.5 (60)

The inner diameter ranged from 0.89 mm to 1.28 mm; consequently, a difference in the lumen flow rate of about 50% between samples can be estimated. It is often underlined that a larger inner diameter can help reducing occlusions, e.g. (6).

Finally, it is observed that the wall thickness shows some differences, varying from 0.22 mm for samples C and E to 0.38 mm for sample B.

Surface characteristics

Concerning surface roughness, all samples showed an average roughness R_a smaller than 1 μm, both on the outer and inner surface and the maximum peaks R_t of about 1 μm. Such values were confirmed by SEM images, shown in Figure 4. Extrusion tracks are visible on the external surface of each sample.

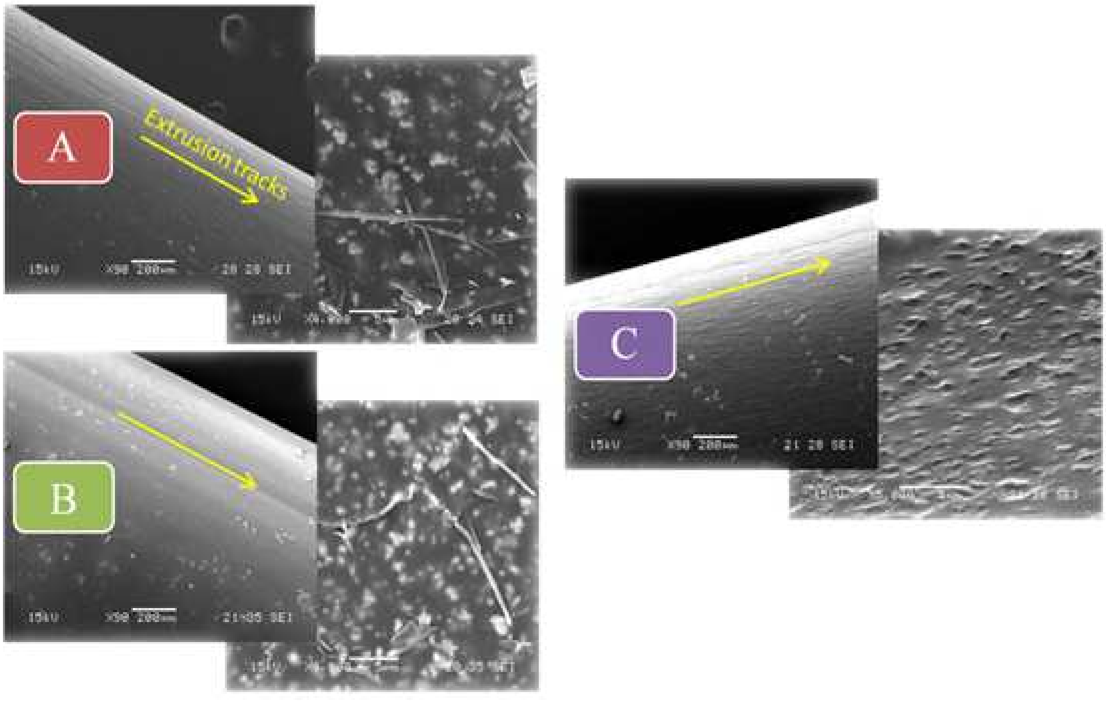


Figure 4: SEM images of the outer and inner side for each PICC. Yellow arrows denote the extrusion tracks that can be noticed on their external surface.

A previous study (7) on urethral catheters showed an inverse relationship between lubricity and surface roughness, (i.e. lubricity increases when roughness decreases), which can be important during PICC insertion and extraction. A possible connection was also questioned between surface roughness and the growth of fibrin over the PICC line surfaces.

Kinking tests

As previously mentioned (Figure 2), results of the kinking test are the critical lengths l_k; It is important to note that the higher the value of l_k, the more prone the PICC is to collapse. Results are reported in Figure 5, indicating large variations among the eight samples, with critical lengths varying from 7 to 22 mm.

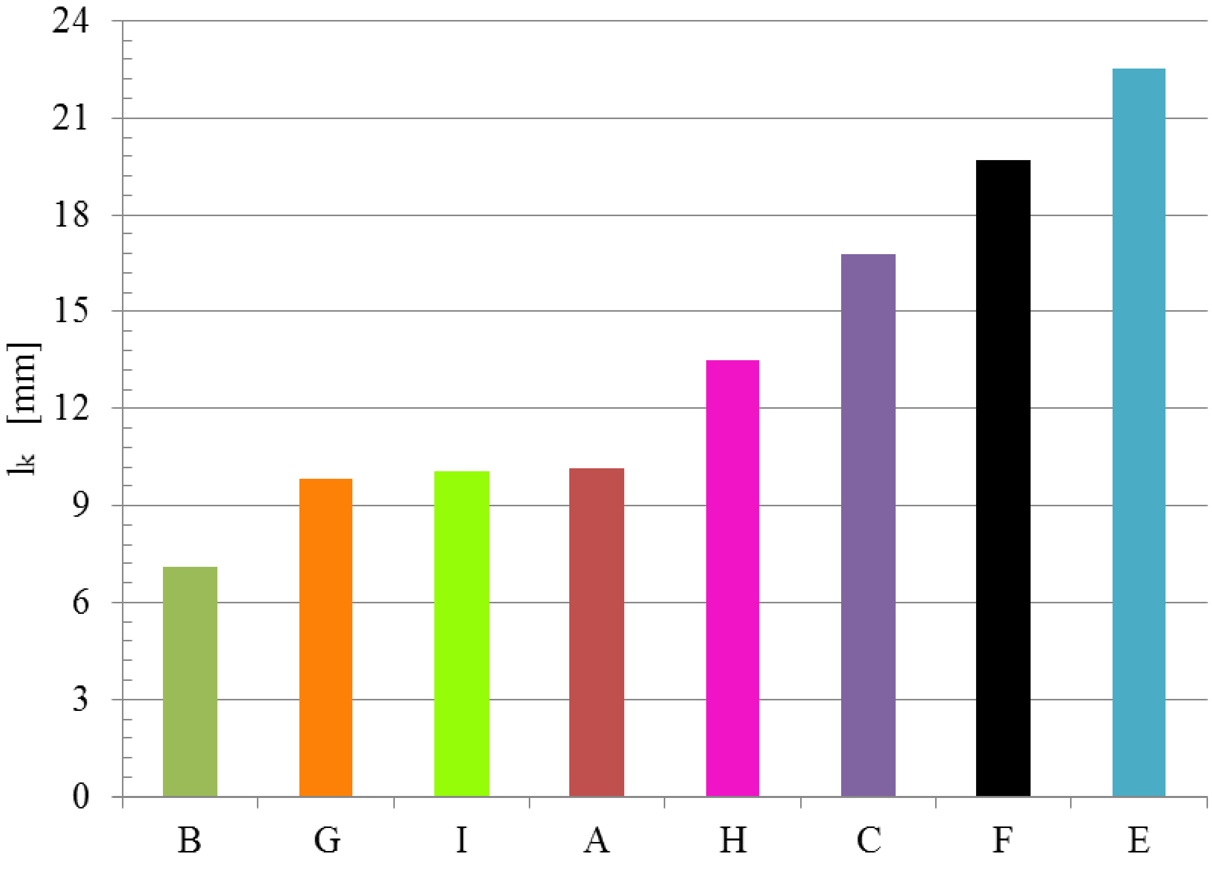


Figure 5: Kinking test results.

Tensile tests

In Figure 6a, the load-strain curves of the catheters are presented, showing a rather remarkable difference from sample to sample, with a wide distribution of the curves. All samples had a non-linear behavior, although elastic almost up to the final strain.

The initial slope of the curves indicates the overall axial stiffness of the PICC, (i.e. $E A_0$ according to Equation 3 in the Background section available online), which is found to vary in a rather wide range, as shown in Figure 6c.

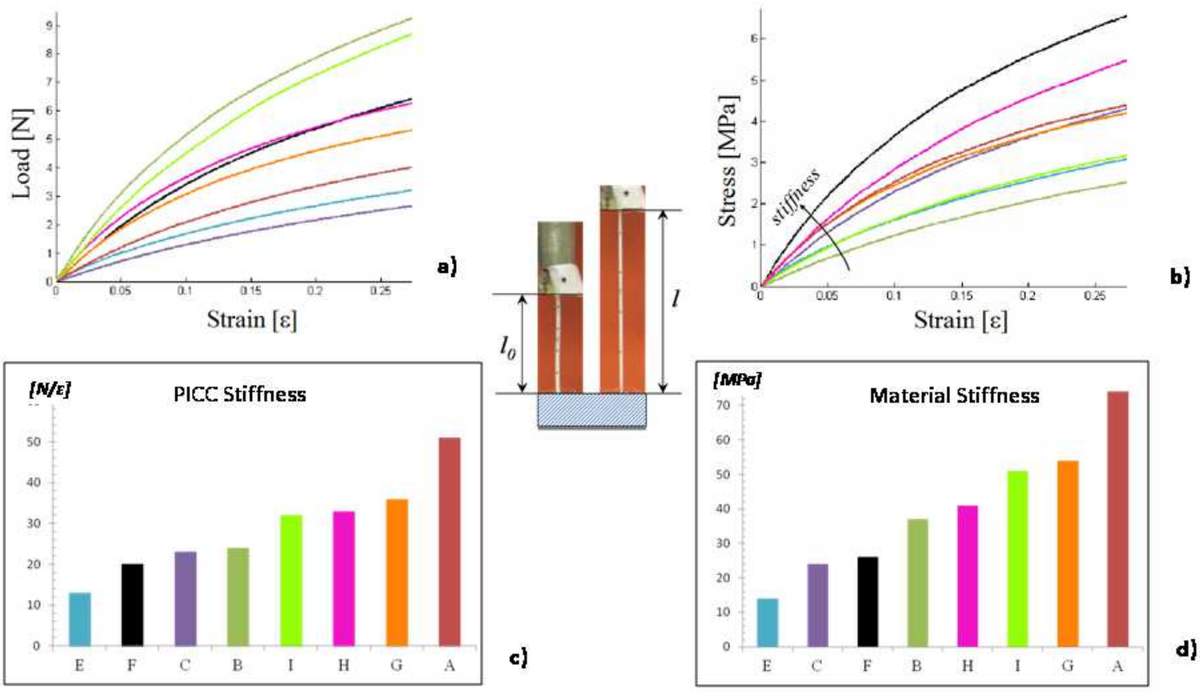


Figure 6: Tensile tests results. a) Load-strain Curves, b) Stress strain curves; Histograms of PICC axial (c) and material stiffness (d).

The catheter axial stiffness is not a function of the material alone, being also influenced by the specimen cross-sectional area (see the Background section available online). Thus, the true material properties are better described by stress-strain curves rather than load-strain curves. Such curves are reported in Figure 6b and show that, as far as the material mechanical behavior is concerned, some PICCs are made of the same or very similarly performing polyurethanes, with some trends overlapping.

The initial slope of the stress-strain curves represents the material stiffness, or elastic modulus (Equation (4) in the Background section), which is plotted in Figure 6d. Notice that the stiffness of both the catheter (Figure 6c) and the material (Figure 6d) vary in a wide range, 13-51 N and 14-74 MPa respectively, and that the sample (color) order is not the same in the two plots, because of the different cross-sections of the samples. Additionally, the initial bending stiffness, *b* in Equation (5) in the Background, was estimated and results are shown in Figure 7. In this case, the influence of the geometry resulted even more important with respect to the axial stiffness; values cover a widespread range.

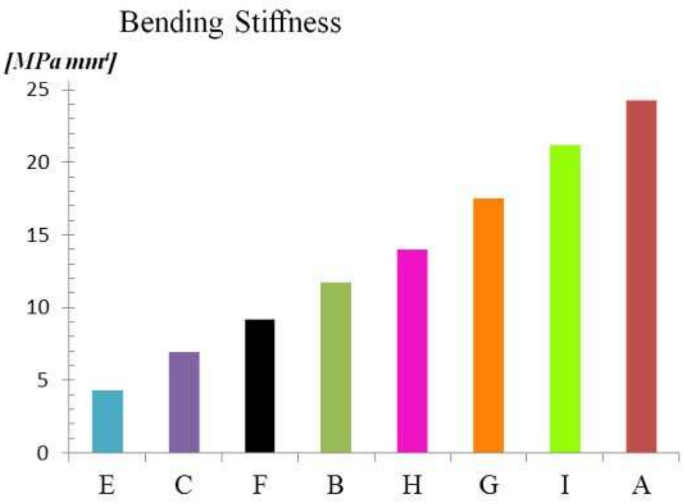
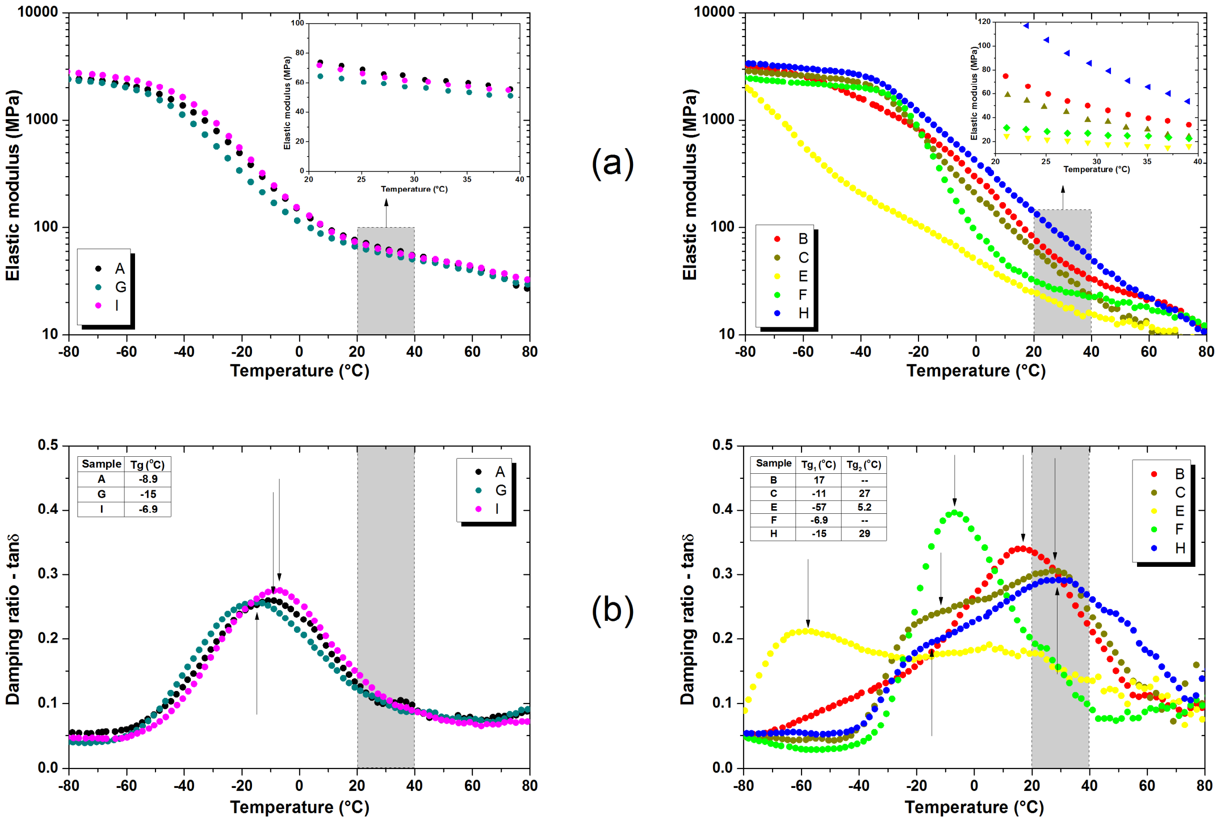


Figure 7: Histograms of PICCs bending stiffness.

It can be underlined that as far as the PICC flexibility is concerned it is not easy to define an ideal stiffness value, because it must fulfil two opposite design requests: to be compliant enough not to damage blood vessels but stiff enough to be inserted and the tip correctly placed in site. The best trade-off is very likely to depend on the specificity of the patient vascular characteristics, and will also affect the mechanical strength of the device.

DMTA tests

Results of DMTA tests on the eight samples are shown in Figure 8. The eight response curves of the elastic modulus vs. temperature have been divided into two distinct groups and reported in two separate graphs. This improves the readability of the results and evidences the existence of a group of three PICCs from different vendors which show very similar characteristics to each other, in contrast to the remaining samples, each of which exhibits its own peculiar behavior.



Sample	Tg (°C)
A	-8.9
G	-15
I	-6.9

Sample	Tg_1 (°C)	Tg_2 (°C)
B	17	--
C	-11	27
E	-57	5.2
F	-6.9	--
H	-15	29

Figure 8: DMTA tests results: a) Elastic modulus b) viscoelastic damping ratio versus temperature. Arrows roughly indicate the positions of the glass transition temperatures, Tg, reported in embedded tables.

In all cases the DMTA response shows a remarkable thermal effect on the material stiffness (Figure 8 a) in the explored temperature range. This is expected for polymeric materials such as polyurethanes, since the presence of substantial amorphous components in their microstructure causes, as the temperature is progressively raised starting from very low values, the transition from a stiffer, elastic and fragile glassy state through a marked viscoelastic behaviour before they melt. Although this so-called glass-transition does not occur suddenly, as for usual first-order phase transitions, it is usual to identify a glass-transition temperature T_g as a characteristic of a given material. As mentioned before, samples A,G and I show very similar trends, at times superimposed, over the whole temperature range, thus leading us to hypothesize that they could really all be derived from the same polymeric material. The minimal differences observed between them might reasonably be attributed to the use of different pigments, plasticizers or other minor additives. By limiting the observations to a temperature range typical for both storage, handling and working conditions of PICCs, such as the 20-40°C interval, it can also be recognized that mechanical properties of catheters of the first group, namely A,G and I, have a slightly higher thermal stability than samples of the second group (B,C,E,F,H). Noteworthy, the properties of materials of the first group remain fairly stable even at higher temperatures, whereas the properties of the other group continue to change significantly, with a steep softening above 40°C. In effects, given the broad variation observed in the elastic modulus, the thermal behaviour of PICCs B,C,E,F and H above 0°C suggest inherent possible issues associated with either packaging, or transport or warehousing. A particular mention must be reserved to sample E, whose softening is observed to start at the lowest temperature and to follow a trend that is more typically found in very compliant rubbery materials rather than in ordinary, although very soft, plastics.

Following the same presentation scheme, curves of the damping ratio vs. temperature are reported in *Figure 8 b* into two separate graphs. All the curves of tan(δ) show the presence of either single or double (samples C,E and H) local maxima, whose occurrence is typically observed in materials that are partially or totally amorphous. The glass transition temperatures T_g can be taken in correspondence of the damping peaks and their values are related to both the chemical nature of the polymer and the average length of its molecular chains. In presence of either multiple polymeric phases or very different molecular segments along the polymer chains, multiple peaks can be observed as occurred for samples C,E and S.

Again, a very similar response is found for samples A,G and I, which further pushes the conclusion that all these may basically consist of the same material. For these samples , the glass transition temperature is rather low (between -7°C and -15°C); for catheters C and H the T_g is located near operation range (25°C and 29.3°C respectively). As previously mentioned, the occurrence of a double Tg in samples C,E and H is probably related to double component/layer/molecular architecture. In particular, on the E side, one may conclude that the material is constituted by a blend of two phases with quite different mechanical behaviours: one rubbery behaviour (low T_{g1}) and one plastic behaviour (higher T_{g2}). Differently, the fact that sample C has a double peak curve may be due to its evident double layered structure, confirmed by SEM images (Figure 9) in which two concentric, distinct layers can be clearly recognized.

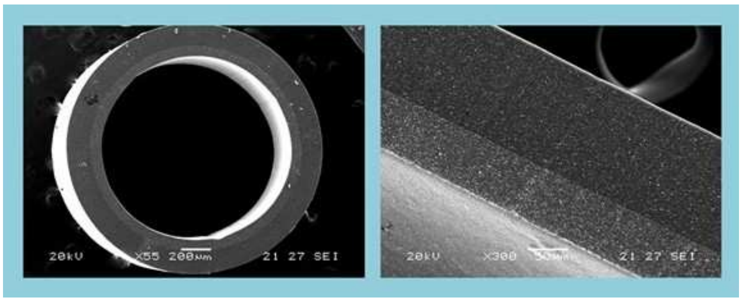


Figure 9: SEM images of the cross-section of sample C.

As a general note, it could be observed that an ‘ideal’ PICC material should have rather constant properties in the range of temperature 20°-40° and it is stable at such temperatures, and also above them.

Conclusions

The present study proposed an experimental comparative analysis of 5 Fr single lumen commercial PICCs from eight different vendors. A procedure was defined, which considered many aspects of the analysis including: kit composition and packaging, macro and micro geometrical features, kinking, tensile and DMTA evaluations.

PICC kits vary significantly among majors vendors. Every kit includes many different items; however, in most cases, a very minor part of them reveals really necessary to the operator. Thus, smaller and more essential kits would be preferred in an attempt to reduce product and logistics costs.

Inside the packages, polyurethane catheters are packaged and protected in many different ways, producing an initial curvature of the catheter which may influence both the kinking strength and the insertion procedure. In some cases, the stylet stiffness can overcome the PICC strength and straighten the initial shape.

Most catheters have a consistent outer diameter, although some vary in the range of 1.64 mm to 1.76 mm; two sample are tapered at the proximal connection for a short length and can reach 2-2.3 mm. Catheters’ thicknesses are also different; consequently, the inner diameter of the lumen may exhibit variations as high as 50%. Concerning the surface roughness and SEM analysis, no relevant differences are found among the samples at a microscopic scale.

The tensile tests reflect the cross-section characteristics of the samples, with force-strain curve varying significantly: at a given strain, the load of the higher curve is nearly four-fold the value of the lower one. As far as the material is concerned, both stress-strain and DMTA plots indicate identical material for some samples. DMTA study reveals also that the thermal behaviour of PICCs may be much different from one another, and that there are some that may be less desirable because of temperature variations.

This study shows the variability of PICC line mechanical properties from vendor to vendor. It also provides general indications that can help the choice of a PICC based on criteria including safety and conditions of use (efficacy).

Acknowledgements: The authors gratefully acknowledge the contribution from the following technical staff from the Dpt. of Civil and Industrial Engineering: Emanuele Del Gratta, Roberto Minelli and Dario Mondini for manufacturing the test rigs, Irene Anguillesi for DMTA tests and Randa Ishak for SEM analyses.

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